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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
WESSENDORF, TERESA D	
ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 12/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/284,107	LOGTENBERG ET AL.	
	Examiner	Art Unit	
	T. D. Wessendorf	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspond nce address --

P riod for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 September 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *2,4,11 and 12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,5-10 and 13-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of Claims

Claims 1-20 are pending in the application.

Claims 2, 4, 11-12 are withdrawn from consideration as being drawn to non-elected invention.

Claims 1, 3, 5-10 and 13-20 are under examination.

Specification

The objection to the disclosure because of the numerous typographical errors has been obviated with the new substitute specification.

The amendment filed 9/2/03 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: "or" such as antibodies at page 1, line 6. The as-filed specification recites proteins such as antibodies, not in the alternative as presently amended.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 1, 3, 5-10 and 13-20 has been obviated with the amendments to the claims and applicants' arguments.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3, 5-10 and 13-20, as amended, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons set forth in the last Office action.

[As a preliminary matter, as indicated in the interview, upon review of the amendments to the claims, withdrawal of the rejection will be made accordingly.

Response to Arguments

A). It is argued that the recited "proteinaceous target" and "peptide" are not unclear to a skilled artisan. The peptides are displayed on replicating packages while the proteinaceous target is the source from which oligopeptides will be derived and contacted with the displayed peptides.

In response, the claims are confusing in that the terms used therein go against the conventional usage in the art. For example, "peptide" is used for those displayed by the replicable packages. Yet, the claims recite immunoglobulin, antibodies, which are known to be proteins, not peptide. This is evident from applicants' newly submitted prior art, Immunology which states that "each chain consists of a series of about ***110 amino*** acids long. Each of these repeats corresponds to a disçrete, compactly folded region of ***protein*** structure known as a ***protein domain.*** Applicants may be their own lexicographer but it carries with it the connotation that they will use terms in the claims that are consistent with the specification and/or prior art.

Applicants argued, that the newly added limitation, "a set" emphasizes that a multiplicity of oligopeptides are to be synthesized and used in the practice of the invention.

In reply, there is nothing in the specification that defines a set as a multiplicity of oligopeptides. Furthermore,

the argued definition reiterates only the term "set". MPEP 714.02 clearly states that applicants specifically point out where support for the argued definition of "a set" as a multiplicity appears in the specification.

B). The rejection of claim 3 has been partly overcome with the amendments to the claims and applicants arguments with respect to the use of candidate peptides. However, the rejection-in-part is maintained for the reasons set forth in paragraph A, above.

C). Applicants have not responded to the rejection of claims 7 and 15 as confusing and broaden the base claim, which does not recite for a gene or genetic sequence in the method. Since applicants have not responded to this rejection, it is believed that applicants are acquiescing therewith.

D). Applicants argue that claims 8 and 16 are directed to the narrower embodiment of the peptides of claims 1 and 3 as scFv as opposed to other possible antibody related peptides. However, it is not clear as to the argued other possible antibody related peptides. Nevertheless, this rejection is withdrawn since the base claims recite several other antibody fragments. [Note that this single chain antibody fragments is the same as the scFv recited in claim 9].

E). Applicants argue that with the additional [act (sic, step] the allegation that the basis for the language must be present in claims 1 and 3 is misplaced.

In reply, this language need not be present as argued. But this language presents ambiguity as the base claim does not recite a sample for the reaction and identification to occur. If this is so, then this claim is a duplicate of claim 3.

F) Applicants urge that the attached Exhibit C defines proteinaceous from a medical dictionary as resembling protein

In reply, the specification at page 1, recites proteinaceous molecules as proteins such as antibodies i.e., definitively a protein and not just resembling a protein. [If this is the definition of said proteinaceous then, the as-filed specification does not contain said definitions and possibly pose a new matter issue]. Furthermore, the response in the last Office action as to the argued page 7, lines 30-33 supports for "target protein" as opposed to a "proteinaceous target or antigen" is similarly incorporated herein. [Applicants state that the scope of proteinaceous target or antigen includes (1) targets and antigens that are composed of both protein component and a non-protein component as well as (2) targets and antigens that are comprised only of protein. In response, a review of the cited section does not recite for the argued non-protein

components and is unclear as to the meaning of the non-protein components. Applicants' arguments are not commensurate in scope with the claims, which do not define the argued non-protein components].

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the method of claim 3 is not positively disclosed in the specification. [Note although claim 3 and the different antibodies are recited in the original claims however, the original specification does not positively disclose e.g., claim 3, specifically as to a candidate peptide].

Response to Arguments

Applicants request that this objection be held in abeyance pending determination of the final language of claim 3 for possible incorporation into the specification, if it still deemed necessary.

In response, in the absence of any amendments or positive recitation in the specification, this objection is maintained.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple

assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3, 5-10 and 13-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims1, 5, 6 of U.S. Patent No. 6,265,150('150 patent) or claims 1, 5, and 6 of U.S. 2002/0132228('228 patent) in view of Middledorp et al.

Each of the '150 Patent and '228 patent discloses a method as claimed except for the use of a set of oligopeptides as the target antigen. However, Middleldorp discloses at col. 7,line 18 up col. 9, line 22 the synthesis of individual antigens or oligopeptides on solid support using the Geysen method. Middeldorp further discloses at col.4, lines 34-50 that the present EBV specific serodiagnosis is accomplished by subjective immunofluorescence tests. Progress to more simple and uniform diagnosis (e.g. ELISA) is hampered because bulk production and purification of viral antigens is not possible using standard virus producing cell lines. This was only

achieved by using alternatively prepared EBV antigen(s). These EBV antigens could be prepared with either genetic engineering techniques or synthetic peptide techniques. Middeldorp further discloses that for the development of a specific and sensitive method to enable a reliable diagnosis to be made in various phases of the infection with EBV it is of great importance to identify immuno-dominant viral proteins and epitopes thereof. Accordingly, it would have been obvious to one having ordinary skill in the art to synthesize multiple (sets) of oligopeptides in the method of each of the Patents in the manner as taught by Middeldorf. The advantages derived in using sets of oligopeptides would provide the motivation to employ sets of oligopeptides. Each of these patents suggests the use of fragments of the antigen proteins in the methods. [Applicants are requested to identify other co-pending applications and/or issued patents that are related or might be interfering with the instant application].

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as anticipated by Barsomian (WO 95/15982) for reasons advanced at page 6, paragraph 18 of the last Office action.

Response to Arguments

In view of the amendments to the claims and applicants' arguments this rejection has been overcome.

Claims 1, 3, 5-10 and 13-20 are rejected under 35 U.S.C. 102(b) as anticipated by Kruif et al (J. Mol. Biol.) for reasons set forth at pages 7-8, paragraph 20 of the last Office action.

In view of the amendments to the claims and applicants' arguments this rejection has been overcome.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3, 5-10 and 13-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Barsomian or Kruif above in view of Middledorp et al (U.S. 5,424,398).

In view of the amendments to the claims and applicants' arguments this rejection has been overcome.

Claims 1, 3, 5-10 and 13-20 are rejected under 35 U.S.C. 102(a) as being anticipated by Burnie et al (Infection and Immunity, 1996) for reasons advanced in the last Office action.

Response to Arguments

Applicants argue that the right columns on pages 1601 and 1603 indicates that there was panning of the phage against each of the three peptides described on page 1601 individually.

In reply, panning was done after the three peptides have been selected or reacted with a series of overlapping nonapeptides as disclosed by Burnie at page 1601, col. 1 bridging col. 2. However, the phage antibody has been reacted with overlapping peptides (set, as claimed), prior to panning. Applicants' attention is drawn to paragraph bridging pages 1600 and 1661. Burnie states that "...the antibody response was further defined to the epitope level by the Geysen technique, as previously applied to the PAC antigen of Streptococcus mutants. The ***derived*** amino acid

sequence was synthesized as a ***series of overlapping oligopeptides*** (i.e., a set as claimed) on pins….Key epitopes, in the form of synthetic peptides, were then used to select scFV from a phage antibody display library derived from a patient with antibodies to S. oralis……." (Emphasis added). Thus, Burnie anticipates the claimed invention.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7924 for regular communications and (703) 308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

T. D. Wessendorf
Primary Examiner
Art Unit 1639

tdw
November 28, 2003